UNITED STATES DISTRICT COURT

DISTRICT OF NEW HAMPSHIRE

UNITED STATES OF AMERICA v. MUSTAFA HASSAN ARIF	)))))))	No. 1:15-CR-57-01-LM

Motion to Dismiss

Defendant Mustafa Arif, through counsel Kirsten B. Wilson and Robin D. Melone respectfully moves the Court to Dismiss Count 1 of the Superseding Indictment, alleging wire fraud in violation of 18 U.S.C. § 1343, Counts 2, 3, 4 of the Superseding Indictment, alleging shipment of misbranded drugs in interstate commerce with intent to defraud, and Count 5 of the Superseding Indictment, alleging misbranding. Mr. Arif moves for an evidentiary hearing on any contested issues of material fact.

In support the following is offered:

Introduction

Count 1 of the superseding indictment charges Mr. Arif with violations of 18 U.S.C. 1343 (wire fraud). Specifically, it alleges that Mr. Arif devised a scheme to defraud and to obtain money by means of false and fraudulent pretenses and for the purpose of executing said scheme he caused CCNow to initiate and cause the transmission of wire transfers of money in interstate and foreign commerce from its bank accounts in Minnesota to bank accounts controlled by Mr. Arif or MAK International in Pakistan and the United Kingdom.

Count 2 of the superseding indictment charges Mr. Arif with violation of 21 U.S.C. 331(a), introducing misbranded drugs into interstate commerce. Specifically, it alleges that Mr. Arif, with intent to defraud and mislead, introduced Anemia Tab, a misbranded drug, into interstate commerce by creating and maintaining the webpage anemia-tab.net, through which visitors could purchase Anemia Tab with services provided by CCNow.

Count 3 of the superseding indictment charges Mr. Arif with a second violation of 21 U.S.C. 331(a), introducing misbranded drugs into interstate commerce. Specifically, it alleges that Mr. Arif, with intent to defraud and mislead, introduced Alzhotin, a misbranded drug, into interstate commerce by creating and maintaining the webpage Alzhotin.com, through which visitors could purchase Alzhotin with services provided by CCNow.

Count 4 of the superseding indictment charges Mr. Arif with a third violation of 21 U.S.C. 331(a), introducing misbranded drugs into interstate commerce. Specifically, it alleges that Mr. Arif, with intent to defraud and mislead, introduced Semtical, a misbranded drug, into interstate commerce by creating and maintaining the webpage Semtical.com, through which visitors could purchase Semtical tab with services provided by CCNow.

Count 5 of the superseding indictment charges Mr. Arif with violating 21 U.S.C. 331(a), introducing misbranded drugs into interstate commerce. Specifically, it is alleged that Mr. Arif, with intent to defraud and mislead, introduced Preleton, a misbranded drug, into interstate commerce by creating and maintaining the webpage Preleton.com, through which visitors could purchase Preleton with services provided by CCNow.

Relevant Facts

On February 2, 2014 Mustafa Arif landed in New York City to attend a shoe exhibition at the New York City Hilton. DHS/HIS Special Agent Alex Miris received a notification that Mr.

Arif was scheduled to arrive. Upon learning Mr. Arif was present in the United States SA David Furtado and SA Alex Miris drafted a criminal complaint charging Mr. Arif with wire fraud. On February 7, 2014 SA Matt Carbone appeared before US Magistrate Judge Dan Lynch in Concord, New Hampshire and swore out the complaint. An arrest warrant issued that same day and New York agents went to Mr. Arif's hotel in New York City and arrested him. Mr. Arif appeared that same day before the United States District Court in New York, where he waived an identity hearing and was ordered transported to New Hampshire by February 21, 2014. On September 9, 2015 the government filed a superseding indictment alleging wire fraud and violations of 21 U.S.C. § 331(a)(2), 352(a) and 353(b)(1) as well as 18 USC § 2, shipment of misbranded drugs in interstate commerce.

It is unclear how Mr. Arif came to the government's attention, but based on notations in discovery some time during 2010 an investigation was launched into Oslo Health Solutions (OHS), a company based in Lahore, Pakistan. The government reports that OHS used approximately 300 websites, each of which was identical in content with only the illness treated and synopsis of the illness changing. (Bates 2). The government alleges Mr. Arif was the primary owner of MAK international, an umbrella company under which smaller companies promoted and sold herbal remedies through creation and maintenance of over 1,500 websites. These websites are the basis for the pending indictments against Mr. Arif. The government alleges that the websites contained false, misleading, and fraudulent representations about the herbal remedies and their ability to cure, mitigate or treat numerous diseases, that the websites are properly categorized as "labeling" pursuant to 21 U.S.C. 321(m) and that the drugs are misbranded.

The government alleges that under the name Oslo Health Solutions, Arif published over 300 websites, "most of which were registered to Oslo Health Solutions." It is unclear how many were not registered to Oslo Health Solutions and to what entity the others were registered. These webpages are reported to offer for sale herbal remedies for a variety of ailments. The websites claimed the products were clinically proven to cure or treat the ailment and that the products were fully guaranteed. The government alleges that the websites included links to clinical research papers, which lead to a page indicating the papers would "soon be posted." The government alleges that the websites within the Oslo Health Network were identical but for the ailment named and the description of the ailment. What the government fails to acknowledge is that the ingredients/formulation for the products do in fact vary.

The government concedes that it has not reviewed each of the approximately 1,500 websites purportedly registered to Mr. Arif. The government focuses their indictment on three "series" of websites: Oslo Health Solutions; Gordon's Herbal Research Center; and Solutions by Nature. Within these series, the government focuses specifically on four remedies: Anemia Tab, Alzhotin, Semtical and Preleton.

COUNT 2 – Anemia Tab

Anemia Tab was advertised as a cure/treatment for anemia. The webpage, anemail-tab.net, included a research link that lead to two clinical study papers. The government was able to identify the authors of these papers as Joy Okpuzor from the University of Lagos and Patrick O Erah of the University of Benin in Nigeria. Once contacted by the government, Ms. Okpuzor and Mr. O Erah confirmed they had written the papers linked to the webpage but said the research had been conducted on Jubi Formula and African Herbal

Formula, not Anemia Tab. Both stated that they had not given permission for the papers to be used to promote Anemia Tab.

The superseding indictment states "no one, other than an undercover law enforcement officer, had ever purchased Anemia-tab." There is no indication that any other individual in New Hampshire or anywhere else in the United States registered complaints about Anemia Tab or was in any way harmed by the use of this herbal product. On or about April 14, 2010 SA David Furtado made an undercover purchase of Anemia Tab, through the webpage www.anemia-tab.net.

This under cover purchase of Anemia Tab is the basis for Count 2 of the superseding indictment.

SA Furtado used software to capture his purchase of Anemia Tab. It appears this video is the only preservation of images of anemia-tab.net. On April 14, 2010 he visited anemia-tab.net. During the video SA Furtado does not click on the "policy" tab at the top of the webpage. Within one minute of entering the page SA Furtado initiates his purchase. This means that neither the defense nor the Court can review or examine the rest of the page, including what information is contained in the various tabs on the webpage, any disclaimers, any information about use or Anemia Tab, or any view of the efficacy claims the government relies upon in filing this indictment.

After initiating his purchase SA Furtado is directed to a CCNow page. He selects "United States" as the shipping country and clicks "check out." He is redirected to a page where he is directed to enter shipping and billing information. After entering his information He hits "continue" at the foot of the page and is directed to a review page. He scrolls to the bottom

of the page and enters his credit card information. Before clicking the "purchase" button SA Furtado must click a box next to acknowledge the following disclaimer:

> I understand and acknowledge the following: (a) actual product packaging and materials may contain more and/or different information than that shown on the website through which the product(s) are purchased; (b) I will read and follow all labels, warnings and directions in connection with using or consuming the product(s) and will contact a health care provider immediately if I suspect I have a medical problem or reaction; (c) the content on this website is for reference purposes and is not intended to substitute for advice given by a physician, pharmacist, or other licensed health-care professional; (d) the product(s) purchased are not intended to diagnose, mitigate, treat, cure or prevent any disease or health condition, and I will not use any information or statements contained on the website through which this product is purchased, or contained on or in such product(s) for such purposes.

Below the "purchase" button it read: "By clicking the 'PURCHASE' button I agree CCNow's Terms of Sale". SA Furtado did not review the terms of sale link. Consequently we do now know what was included in those terms of sale.

After clicking "purchase" SA Furtado is redirected to a confirmation page. The government provided email confirmation of the order, which includes the same warning stated above.

It is worth noting that the government has provided what appears to be the "policy" page of the webpage for Vitiligo Tab, a page they allege to be identical to that for Anemia Tab. The page includes information about the guarantee. Also included on that page is a "Legal Disclaimer" which reads as follows:

> Vitiligo Tab has been manufactured and consumed for years. There are no known side effects to date. The product is a herbal medicine and is not regulated by the FDA. In the unlikely case of adverse reaction, stop use and consult your doctor or physician immediately. All information in this site should be taken as advise and not as a substitute for professional medical assistance.

This purchase of Anemia Tab is the basis for Count 2 of the superseding indictment.

COUNT 3 - Alzhotin

On August 5, 2010 SA Furtado accessed www.alzhotin.com and placed an under cover order for Alzhotin, determined to be part of the Gordon's Herbal Research Center (GHRC) network of websites. SA Furtado wrote in his report that the website claimed Alzhotin was "specifically formulated to treat Alzheimer's Disease."

As with his purchase of Anemia Tab, SA Furtado recorded his purchase of Alzhotin. After clicking on the "about Alzhotin" tab at the top of the page, SA Furtado initiated his purchase. He did not click on the "legal disclaimer" tab at the foot of the page. Upon initiating the purchase SA Furtado was redirected to the same CCNow page to which he had been redirected for his purchase of Anemia Tab. As with the Anemia Tab purchase SA Furtado was required to check the box next to the disclaimer, identical to that from the Anemia Tab purchase. Again, below the "purchase" button it read: "By clicking the 'PURCHASE' button I agree CCNow's Terms of Sale". SA Furtado did not review the terms of sale link.

The purchase was received on September 22, 2010 and the contents were submitted to FCC for analysis. In December, 2010 the analysis was returned to SA Furtado reporting that, "the concentration of metals found in the product, including vanadium, chromium, cobalt, nickel, arsenic, selemium, cadmium, mercury, thallium, and lead, were less than 1.2 micrograms per gram." The analysis also showed that the labeled ingredient haloperidol was not found in the sample. Reserpine was identified in the sample. There is no interpretation for this analysis. The government has not provided the labeling, or packaging for Alzhotin.

Of the 1,500 webpages the government relies upon to support its indictment, it has preserved images of approximately 500. It did preserve images of Alzhotin.com. The following is observed at the foot of each page of the website: "Information, statements and products on this website have not been evaluated by the FDA and are not intended to diagnose, mitigate, treat, cure, or prevent any disease or health condition." Additionally, the website for Alzhotin includes a separate "legal disclaimer" which reads as follows:

> Information on this site is provided for information purposes and is not meant to substitute for the advice provided by your own physician or other medical professional. You should not use the information contained herein for diagnosing or treating a health problem or disease, or prescribing any medication. You should read carefully all product packaging. If you have or suspect that you have a medical problem, promptly contact your health care provider. Information and statements regarding dietary supplements have not been evaluated by the Food and drug Administration and are not intended to diagnose, treat, cure, or prevent any disease.

The government provided an order confirmation emailed after the order was placed. Included on the confirmation is the following:

> I understand and acknowledge the following:
> - actual product packaging and materials may contain more and/or different information than that shown on the website through which thte product(s) are purchased;
> - (b) I will read and follow all labels, warnings and directions in connection with using or consuming the product(s), and will contact a health care provider immediately if I suspect I have a medical problem or reaction;
> - the content on this website is for reference purposes and is not intended to substitute for advice given by a physician, pharmacist, or other licensed health-care professional;
> - (d) the product(s) purchased are not intended to diagnose, mitigate, treat, cure or prevent any disease or health condition, and I will not use any information or statements contained on the website through which this product is purchased, or contained on or in such product(s) for such purposes.

This purchase of Alzhotin is the basis for Count 3 of the superseding indictment.

COUNT 4 - Semtical

The government created a spreadsheet of New Hampshire customers who had made purchases from MAK websites (Bates 121). The government reached out to two of these individuals and arranged to meet and interview them. On February 6, 2013 SA Furtado and investigator Carlice Ducey met with T.F. and P.S. in Manchester, NH. P.S. reported that he had been diagnosed with inclusion body myositis and in 2011 he started exploring herbal and holistic options for treatment. To avoid telling his wife he was exploring holistic options, he enlisted T.F. to help because T.F. believes in holistic medicine. While using an internet search engine (they did not recall which one) they came upon a webpage for Semtical sold by Solutions by Nature and placed an order. P.S. recalled the webpage said it would "improve symptoms" and believed the research information, "claimed to cure the disease." (Bates 122). The package arrived 3-4 weeks later at T.F.'s home and she gave it to P.S.

Neither P.S. nor T.F. had any other specific recollections of the webpage. When asked if the package arrived from Pakistan T.F. did not recall. When shown a sample address label for MAK International T.F. said it "looked familiar" and remembered the package had in fact come from Pakistan. P.S. reported that he saw no improvement with use of Semtical. He did not report any negative side effects.

T.F. was able to provide SA Furtado with purchase confirmation received to her email address. Included with the purchase confirmation was the following disclaimer:

> I understand and acknowledge the following:
> (a) actual product packaging and materials may contain more and/or different information than that shown on the website through which the product(s) are purchased;
> (b) I will read and follow all labels, warnings and directions in connection with

using or consuming the product(s), and will contact a health care provider immediately if I suspect I have a medical problem or reaction;

(c) The content on this website is for reference purposes and is not intended to substitute for advice given by a physician, pharmacist, or other licensed health-care professional;

(d) The product(s) purchased are not intended to diagnose, mitigate, treat, cure or prevent any disease or health condition, and I will not use any information or statements contained on the website through which this product is purchased, or contained on or in such product(s), for such purposes.

(Bates 125.)

The government provided images of semtical.com, the webpage for Semtical. At the foot of every page of Semtical.com is a green banner, which includes a link labeled "Disclaimer." Clicking on "Disclaimer" leads to the following warning:

> Information provided on Semtical.com about medical conditions, symptoms, and related products is not intended to be a substitute for professional medical advice. Visitors to this site should not use this information to diagnose or treat a health problem, symptom, concern or disease without consulting with their individual qualified healthcare provider. Statements contained on this web site have not been evaluated by the FDA. Semtical.com products are not intended to diagnose, heal, cure or prevent disease.

Next to the "Disclaimer" link is a link labeled "Terms and Conditions" which includes the following under, "Disclaimer and Limitation of Liability."

> Semtical.com. provides this Site and its content on an "As Is" and "As Available" Basis, and makes no representations or warranties of any kind with respect to these sites or its contents. Semtical.com disclaims all such representations and warranties, either express or implied, including without limitation warranties of merchantability, fitness for a particular purpose, and non-infringement. In addition, Semtical.com does not represent or warrant that the information on this site is accurate, complete or current. To the fullest extent permissible pursuant to applicable law, neither Semtical.com nor any of its directors, employees, representatives, or any party involved in creating, producing, or delivering this Site will be liable for any direct, incidental, consequential, indirect, or punitive damages arising out of or in connection with the use of this Site. The sole and entire maximum liability Semtical.com and any of the providers of information, products, or services, for any reason, and your sole and exclusive remedy for any cause whatsoever, shall be limited to the amount paid by you for the information, product or service purchased. The limitation of damages set forth above are fundamental to the basis of the bargain between you and Semtical.com. The goods and services provided from this site would not be provided without such limitations.

There is no research link on Semtical.com.

This purchase of Semtical is the basis for Count 4 of the superseding indictment.

COUNT 5 – Preleton

In July, 2010 agents made an under cover purchase of Preleton from the website Preleton.com, attributed to the GHRC network. The product arrived in August 2010. As with the purchase of Anemia Tab and Alzhotin, the purchase of Preleton was captured by video. On preleton.com, the agent clicks on links titled "usage instructions", "ingredient details", and "expected results". He then clicks on a tab in the upper portion of the page titled "research" but does not click on what appears to be a link to a paper. He clicks on "testimonials" at the top of the page. He clicks on "contact". The viewer never gets to see the "home" version of the page that a visitor would first see.

The agent initiates his purchase by clicking on the "order now" tab at the top of the webpage. As with the other under cover purchases the agent is redirected to a CCNow page. The warnings visible on the page for the Anemia Tab and Alzhotin purchases are visible here in identical form. As with the other sales the agent did not review the terms of sale link. Having used PayPal to complete the purchase the agent was directed through a series of PayPal pages before reaching the final CCNow confirmation page, which was identical to those seen after earlier purchases.

Provided in discovery are email confirmations, identical to those provided for the other purchases and containing the same disclaimer.

Reports indicate that an invoice was included with the package but this invoice has not been provided to the defense. (Bates 3677). The government has not preserved, or if it has preserved it has failed to provide to the defense, captured images of the webpage

preleton.com. Consequently the only images available for review are those in the video. The exception is one image of what could be the homepage for preleton.com. At the foot of the page is the following labeled "Legal Disclaimer":

> The statements made on our websites have nt been evaluated by the FDA (U.S. Food & Drug Administration). Our products are not intended to diagnose, cure or prevent any disease. If a condition persists, please contact your physician. The information provided by this website or this company is not a substitute for a face-to-face consultation with your physician, and should not be construed as individual medical advice. The testimonials on this website are individual cases and do not guarantee that you will get the same results.
>
> It is unknown if this disclaimer was at the foot of every page.

This purchase is the basis for Count 5 of the superseding indictment.

Count 1 – wire fraud

Discovery provided to date does not include a list of every webpage purportedly created and maintained by MAK International nor does it include images of all the pages specifically referenced. After initially directing counsel to use The Way Back Machine, an internet archive that occasionally and in no consistent fashion, saves copies of webpages, the government provided CDs of captures taken in 2011 of the homepage of approximately 500 of the alleged 1,800 websites.[1]

Based on a memo sent to prior counsel, the government bases its wire fraud indictment upon what they allege to be a scheme to defraud based on creation of websites that contained falsified clinical studies and other false statements regarding clinical data for the purpose of inducing customers to purchase the drugs offered for sale on those pages.

Legal arguments:

[1] The government estimates the total number of webpages inconsistently, reported as 1,500 in some places and 1,800 in others.

1. The written acknowledgement that each customer must sign that they are not purchasing the products to cure, treat or mitigate any disease or condition negates any allegation of fraud.

2. The herbal and homeopathic remedies at issue in Counts 2, 3, and 4 are not prescription drugs.

3. Any allegations of misbranding are based in advertising, not labeling and, therefore, must be dismissed because the Federal Trade Commission has exclusive jurisdiction over false, deceptive or fraudulent advertising of non-prescription drugs pursuant to 15 USC 52-57.

4. Under 15 USC 52-57 the Federal Trade Commission has exclusive jurisdiction over false, deceptive or fraudulent advertising of non-prescription drugs; characterization as a "scheme to defraud" under the wire fraud statute does not vest jurisdiction in the courts.

5. Where there is no intent to misrepresent FDA approval there can be no specific intent to defraud rooted in claims of efficacy because efficacy is a measure.

6. Where drugs belong to a bona-fide school of medical practice sincerely believed an intent to defraud does not exist.

Relevant statutes

Title 21 USC §321(g)(1) defines a "drug" as, "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; . . . and articles (other than food) intended to affect the structure of any function of the body of man or other animals. . ."

Under Title 21 USC §353(b)(1)(a) a drug "prescription if, "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug."

Title 21 USC § 331(a) prohibits introduction or delivery for introduction, or causing the introduction or delivery for introduction, into interstate commerce of any drug that was misbranded.

Title 21 USC §352(a) states that a drug is misbranded if its labeling is, "false or misleading in any particular." "Labeling" is defined as, "all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such articles." 21 USC §321(m). Pursuant to 21 USC §353(b)(1) a drug is also "misbranded" if it is a prescription drug dispensed without prescription of a licensed medical practitioner.

A "material" fact or matter is one that has a natural tendency to influence or be capable of influencing the decision of the decision maker to whom it was addressed.

I. <u>The acknowledgement that each customer must sign that they are not purchasing the products to cure, treat or mitigate any disease or condition negates any allegation of fraud.</u>

There was no intention to sell Anemia Tab, Alzhotin, Semtical, Preleton, or any other herbal remedy as a drug or for use as a drug. Every purchase of an MAK International product was processed by CCNOw. Before finalizing their purchase, customers were required to actively acknowledge (among other things) that the product their were purchasing was not intended to diagnose, mitigate, treat, cure or prevent any disease or

health condition and further attest that they will not use information on the website through which the product was purchased to diagnose, mitigate, treat, cure or prevent any disease or health condition. This process is clearly visible in the three under cover purchases executed by the government. It was impossible for a customer to complete a purchase without making this statement and agreeing to not use the product as a drug. It is a rational inference that all other customers were required to make the same affirmative statements to complete their purchases, as CCNOw was the only venue for purchase.

The required and proactive statement by all consumers that they would not use the product as a drug, especially when accompanied by the numerous disclaimers on the various webpages, negates any allegation of fraud premised on efficacy.

The attestations required in this case are similar to those at issue in United States v. Goldberg. 538 F.3d 280 (2008, 3d Cir.) In Goldberg , the defendant was charged with wire fraud and misbranding along with other criminal charges. The defendant was distributing veterinary prescription medication to customers, and had disclaimers which required the customers to agree to certain stipulations before making online purchase of veterinary drugs from the defendant. On appeal, Goldberg argued that the disclaimers negated any "intent to defraud." The Court specifically noted that, ". . . [t]he Government overlooks that the Disclaimer is not an affirmative representation by Goldberg, but rather by the customer, meaning that any misrepresentations occasioned by the statements was caused by the customer lying about the applicable law in his or her home state, not the misbrander (Goldberg) that merely received the statement. As a result, it cannot be said that Golderg mislead anyone via the statements his customers made." Id. at 289. The Court further reasoned that even in the presence of statements to the contrary in website advertising,

"[A]gent Tremaglio was repeatedly told that the drugs he was ordering would not be provided pursuant to a prescription, were not prescribed by a veterinarian, and that he would not be able to consult directly with one either before or after he placed his order. As a result, the only way that we could deem Goldberg's conduct misleading would be to hold that when a vendor permits outdated sales literature to continue to exist in some form, even though it told customers not to rely on the representations therein, the vendor has misrepresented its activities. We are not prepared to do this, and therefore we deem that this argument does not justify Goldberg's felony convictions." Id. at 289. The acknowledgement that the customers sign in this case show that both parties, the seller and the customer, were aware that the products were not sold or intended to be used as drugs, and therefore, the government cannot prove the requisite intent.

II. The herbal and homeopathic remedies at issue in Counts 2, 3 and 4 are not prescription drugs.

The government specifically alleges that three herbal remedies are prescription drugs under 21 USC 353(b)(1)(a): Anemia Tab, Semtical and Alzhotin. The government alleges that the website for each included, ". . . false information relating to efficacy of the drugs, a list of ingredients or the drugs, information about side effects and other information pertinent to the use of the drugs." (superseding paragraph 29).

Counts 2, 3 and 4 generally allege that the subject substances are prescription drugs by including a reference to 21 U.S.C. 353(b)(1)(A) which states that a drug intended for use by man which, "…because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use it is not safe for use except under

the supervision of a practitioner licensed by law to administer such drug." (superseding paragraph 31).

There is no specific allegation as to why Anemia Tab, Alzhotin, or Semtical (or any of the other hundreds of substances referenced in the paragraphs 1 through 24 of the indictment) is prescription. Neither the indictment nor the discovery contains analysis of the toxicity of these herbal remedies either individually or in compound. Nothing alleges that these substances are toxic in any dose or quantity. Nothing alleges that there are risks of side effects. The government has offered nothing in support of their bald assertions that use of these substances is only safe under supervision of a licensed medical practitioner because of toxicity or potential for harmful effects, method of use or collateral measures necessary for use. 21 USC § 353(b)(1)(A). At best, the government has alleged that these herbal remedies do nothing. For this reason, the Court must find that the drugs are not prescription drugs under 21 U.S.C. 353(b)(1)(A) and must dismiss these counts.

Title 21 U.S.C. 231(ff)(1) states that a dietary supplement, "means a product . . . intended to supplement the diet that bears or contains one or more of the following dietary ingredients", which list includes (C), herbs and other botanicals. Under 21 U.S.C. 231(ff) dietary supplements, including herbs and botanicals, are not prescription drugs but are marketed as consumable food products. Herbal remedies otherwise considered safe for consumption as dietary supplements and health food products do not become prescription drugs solely by virtue of their promotion to treat a serious ailment, even if deemed ineffective in treating the ailment. To allege that the same herbs which, in one chapter of the Code are safe for consumption, become toxic and prescription simply by nature of their

categorization is illogical. The inherent toxicity of a substance does not change simply because of its promotion as a drug.

III. Any allegations of misbranding are based in advertising, not labeling and, therefore, must be dismissed.

The government has alleged that the websites created and maintained by Mr. Arif and MAK International are "labeling" as defined in 21 U.S.C. 352(a). "Labeling" is defined as, "all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such articles." 21 USC §321(m).

The superseding indictment alleges that the websites for Anemia Tab, Alzhotin, Semtical , and Preleton, offered the drugs for sale, "were directed to potential purchasers" and included false information about efficacy, a list of ingredients, information about side effects and, "other information pertinent to the use of the drugs." (superseding para 29). As with other aspects of the indictment, the government has failed to specifically allege what on the websites constituted "other information pertinent to the use of the drugs." Because they have failed to preserve the entire websites, Mr. Arif has no means to meaningfully confront these allegations. Furthermore, the government has provided the shipping material packing material and bottle for only one of the substances it alleges (Anemia Tab).

Mr. Arif does not dispute that "labeling" is not restricted to labels on or in the article or package that is transported. Kordel v. U.S., 335 U.S. 345, 347 (1948). He concedes that in some instances websites may constitute labeling. Not all websites, however, constitute labeling and the existence of a website serving to advertise a product does not automatically become labeling.

Even in a non-prescription drug context, when advertising literature also serves as labeling, the advertisement itself does not become labeling. "Advertising and labeling circulars may be the same and yet perform two offices of advertising and labeling; courts have jurisdiction over labeling function, whereas Federal Trade Commission would have jurisdiction at same time over same circular because of its advertising function. " United States v Paddock, 67 F Supp. 819 (1946, DC Mo).

In assessing whether materials are labeling or advertising, the courts have considered, among other things, the purpose and targeted reader. In Kordel v United States the defendant company had marketed and sold various health products. 335 U.S. 345 (1948). He shipped these products to various outlets for sale. He either separately or concurrently shipped pamphlets and circulars to vendors, intended to accompany those products. Id. at 346. The question presented in the case was whether the pamphlets/circulars constituted labeling. The Court found that in that case the literature was labeling, focusing in part on its purpose. "It explained their uses. Nowhere else was the purchaser advised how to use them. It constituted an essential supplement to the label attached to the package. Thus, the products and the literature were interdependent. . ." Id. at 348. "Advertising" is aimed at "potential purchasers to induce the purchase." New York State Pesticide Coalition, Inc. v. Jorling, 874 F.2d 115, 119 (2nd Cir, 1989). This is contrasted with "labeling" which is aimed users of the product, not the general public." Kordel at 345.

The websites at issue here differ significantly from the literature in Kordel. In Kordel pamphlets/paper literature was used in the promotion of the drug but also was the sole source of information on how to use the drugs. "No where else was the purchaser advised how to use them." Id. at 348. The pamphlets were necessary to the end user. The

websites here are not necessary to the end user – they are not "interdependent" as was the case in Kordel. (335 U.S. at 348).[2]

The websites here were clearly intended to market the products. For that purpose they included ingredients and other various information about the drug. They were directed to potential customers, not necessarily the end user of the products. If the customer never again referred to the website, he/she could use the drug based solely on what was on the bottle.

Nor does Mr. Arif dispute that the Court maintains jurisdiction over advertising that serves a dual purpose as labeling. "The fact that, in the evolution of the Act, the ban on false advertising was eliminated and its control was transferred to the Federal Trade Commission did not eliminate from the Act advertising which performs the function of labeling. Kordel v. United States, (335 US 345, 351) (1948).

Even assuming, arguendo, that the websites constitute labeling, they are also advertising. The government's allegations of intent to defraud are based in false efficacy claims which it would be hard pressed to argue serve a labeling function. To the extent the websites are both labeling and advertising (again, Mr. Arif does not concede the labeling function) the court's jurisdiction over the labeling function does not extend to the advertising function of the website, jurisdiction over which lies with the FTC.

When, as here, the website's primary function is advertising (not labeling) the Court should decline to exercise jurisdiction and, instead, defer to the administrative scheme established in under the FTC.

[2] The Defense has requested images of all packaging materials and labeling in their possession. At the time of filing this information has not been received.

IV. Under 15 USC 52-57 the Federal Trade Commission has exclusive jurisdiction over false, deceptive or fraudulent advertising of non-prescription drugs and characterization as a "scheme to defraud" under the wire fraud statutes does not vest jurisdiction in the courts.

The distinction between puffery, falsehood, deceptiveness and fraud in the field of medical advertising is not simple. In choosing to avoid unwarranted and unjust criminal prosecutors of businesspersons, Congress vested exclusive control with the FTC. During comprehensive revisions of the Food and Drug laws in 1938, Congress specifically deprived courts of criminal jurisdiction over businesspersons accused of fraud rooted in false advertising claims of medicines. The statutory framework articulated in 15 USC 52-57 gives exclusive control to the Federal Trade Commission. Prescription drugs were later exempted from this statutory scheme in 1962 (See 21 USC 352(n)).

The prohibition on false advertising of food, drugs and cosmetics is stated in 15 USC § 52, while criminal penalties for such action with intent to defraud are described in 15 USC § 54. Congress enacted a specific and comprehensive statutory scheme to address fraud rooted in false advertising of OTC drugs. The scheme requires certification of facts to the Attorney General for establishing liability for criminal fraud penalties. 15 USC § 56(b). "Under § 14, violations of § 12 that were willful or committed in connection with the sale of injurious products were made punishable as misdemeanors. Under § 5(l) the government was authorized to recover a civil penalty from any defendant who violated a final FTC cease and desist order. But under § 16, these punitive measures were conditioned upon FTC certification to the Attorney General of probable liability." Holloway v. Bristol-Myers Corp *(*485 F.2d 986, 994) (DC Cir, 1972).

"Congress voiced approval of the Commission's record in shaping the fluid contours of generalized statutory policy pronouncements into meaningful and coherent rules of business conduct, and it felt that the agency's experience in making concrete the proscriptions of the 1914 Act against 'unfair methods of competition' rendered the FTC particularly well suited to the responsibility of giving life to the broad standard of 'deceptiveness' as applied to advertising." Gladys G. Holloway v. Bristol-Myers Corp. (485 F.2d 986, 995-996) (DC Cir, 1972).

The following legislative history excerpt, offered in Bristol-Myers Corporation, *supra,* is illustrative of Congressional intent in placing false advertising with the FTC. Footnotes 48 and 49 read as follows:

> (48) H.R.Rep.No.1613, 75th Cong., 1st Sess. at 5 (1937): The definition is broad enough to cover every form of advertisement deception over which it would be humanly practicable to exercise governmental control. It covers every case of imposition on a purchaser for which there could be a practical remedy. It reaches every case from that of inadvertent or uniformed [sic] advertising to that of the most subtle as well as the most vicious types of advertisement. Obviously, a definition to be applied to the infinite variety of advertisements disseminated regarding thousands of different foods, drugs, devices, and cosmetics must be general in its terms. There will be difficulties and uncertainties of interpretation just as there have been in the case of provisions of the Federal Trade Commission Act, the Food and Drug Act, and the antitrust laws, and other laws prescribing in general terms standards of conduct to be applied to innumerable factual situations. These difficulties are inherent in the problem but should not prevent necessary and adequate consumer protection.
>
> (48, continued) Remarks of Rep. Lea, co-sponsor of the Wheeler-Lea Amendment, 83 Cong.Rec. 392 (1938): We have, therefore, the question of applying the remedies to a definition very broad in its terms. The procedure of the Federal Trade Commission . . . is well calculated to discriminate between the various classes of offense against this section [§ 12] without injustice. (See Hearings on H.R.3143 Before the House Comm. on Interstate & Foreign Commerce, 75th Cong., 1st Sess., at 46-47 (Remarks of Rep. Martin & Chairman Lea) (1937); Hearings on S. 3744 Before the Senate Comm. on Commerce, 74th Cong., 2d Sess. at 79-80 (Statement of R. E. Freer, Member, FTC) (1936); Hearings on S. 3744 Before the House Comm. on Interstate & Foreign Commerce, 74th Cong. 2d Sess. at 89-90 (Memorandum of Charles H. March, Acting Chairman, FTC) (1936).)

(49) Remarks of Rep. Lea, 83 Cong.Rec. 392, 406 (1938): . . . . A large class of businessmen who have never been subject to criminal procedure will have the opportunity to go to the Federal Trade Commission and conform to the requirements of the law without being brought into court or branded as criminals. . . . . . . The great majority of people who advertise want to do the right thing, and if the Government points out to them where they are making a mistake and are in violation of the law, they are willing to conform to the law. The man with good intentions should not be penalized before he has had a chance to correct his mistake. * * * . . . [Strict liability for false advertising] is not a practical way to deal with businessmen. [It would] destroy the principal virtue of the Federal Trade Commission procedure, which is to give the honest businessman a chance to adjust his differences without harassing him or bringing him into court, with the expense involved by such proceedings.

(49, continued) Remarks of Rep. Halleck, 83 Cong.Rec. 401 (1938): I believe there is another reason why the Federal Trade Commission is the proper authority to have this power. These provisions . . . are generally the subject of quasi judicial action and determination, with decisions to be made affecting the rights not only of consumers but of producers and distributors. The Federal Trade Commission is a quasi judicial organization. It is independent and goes on year after year pursuing its activities. . . . . . . Something has been suggested here [in debate] about the broad language of this act. It is not definite. There is no catalog of the offenses sought to be reached. It was pointed out to the committee that only by the use of broad language would the Commission . . . have any real opportunity to accomplish any real results. . . . The very fact that broad language is used should indicate to all of us . . . that we should not in every case inflict a criminal penalty or a civil penalty . . . upon any person who happens unintentionally to violate the act. S.Rep.No.361, part. 2, 74th Cong., 1st Sess. 9 (1935) (Minority Views). (Emphasis Added)

The statement of purpose accompanying H.R.Rep.No.1613, 75th Cong., 1st Sess. at 2 (1937) (the House version of the bill ultimately was adopted by the Conference Committee) is illustrative of the thought behind adoption of the final legislation (15 USC 52-57). “The common motive of false advertisement is the same in every line of industry, to gain an economic advantage through defrauding or misleading the purchaser. This method of protecting the public should be harmonized and unified under one organization with consistent and uniform methods of enforcement and penalization. Efficiency, uniformity, and economy suggest this course. The legislation is framed with that purpose in mind. The

Federal Trade Commission as an independent quasi-judicial body, has a procedure better calculated to handle multitudinous types of advertising and to do its work to greater confidence and satisfaction of the public than any purely administrative body…"

Senator Wheeler further explained, "The committee held long hearings. After having held these hearings, they took up the definition of false advertisement with reference to food and drugs, and they took the definition of advertisement from the bill which the Senator from New York had drafted, and they said, "The place to put this is under the Federal Trade Commission, because in the Federal Trade Commission there is developed an orderly procedure, the same kind of procedure as obtains in courts of law". They said that was the proper place for it rather than to give arbitrary power to some bureaucrat in a department. Then too they doubtlessly felt that further control of advertising should be under that agency which has always had jurisdiction. The Food and Drug Administration has never had jurisdiction over any advertising." 83 Cong.Rec. 3291 (1938)

Congress deliberately left jurisdiction with the FDA in some other situations, demonstrating further their intent to excise advertising from their control. "The fact that, in the evolution of the Act, the ban on false advertising was eliminated and its control was transferred to the Federal Trade Commission did not eliminate from the Act advertising which performs the function of labeling. " Kordel v. United States, 335 US 345, 351 (1948). Advertising for prescription drugs is under FDA jurisdiction. 21 USC 352(n).

The scenario currently before the Court falls into no specifically delineated exception that removes jurisdiction from the FTC and places it with the Court.

V. In absence of any intent to misrepresent the lack of FDA approval of the drugs there can be no specific intent to defraud

The government repeatedly alleges that the websites, "offer herbal products that fraudulently claim to treat or cure a variety of serious health conditions/illnesses . . ." (Bates 67). The government alleges generally that the websites, "included false information relating to efficacy of the drugs, a list of the ingredients of the drugs, information about side effects, and other information pertinent to the use of the drugs". In reality the government has shown that a handful of websites contained false research papers. And while some websites did include information referencing clinical studies, any such representations are qualified by the plain language and prominently exhibited disclaimers that the products are not FDA approved.

There is a fine distinction between puffery, deceptiveness and fraud in marketing. This distinction is even finer when the purveyor has a fundamental belief in the efficacy of the product for sale. The government appears to be asserting that the alleged false statements are material in one of two manners; either (1) they have the ability to induce purchases of non-FDA approved drugs by knowing consumers of non-FDA approved drugs or (2) the statements need not be material so long as they are false. In other words, if Mr. Arif purposely made false claims of possession of scientific proof in his promotional literature to induce purchase of the drugs, this is sufficient to prove criminal intent to defraud.

In light of the repeated disclaimers on the websites and emailed order confirmations, these arguments must fail. A review of the various images of the pages made available by the government demonstrates that at worst, Mr. Arif used false statements to advertise his products. At most, these allegations rise to the level of false advertising or misbranding by way of mislabeling under the FDCA, charges the government has opted to not pursue.

The government specifically alleges that Anemia-tab.net includes a link to a plagiarized clinical study paper. The images preserved do not show false statistics or rates of efficacy. The images preserved, as well as those of vitiligo-tab.net, which the government alleges to be identical, *do* show repeated disclaimers, notifying purchasers that the websites is not a substitute for medical advice and is not to be used to diagnose, treat, cure, or prevent any disease. The page also makes it clear that the product is not FDA regulated.

As described above, the webpage for Alzhotin has a pinned notice at the foot of every page that states the statements and products have not been evaluated by the FDA and are not intended to diagnose, mitigate, treat, cure or prevent any disease. A legal disclaimer similar to that on anemia-tab.net is included, stating that purchasers should seek the advise of a medical professional. There are no claims links to research papers, no percentages or statistics intended to portray claims of clinical study proving efficacy.

The webpage for Semtical includes disclaimers, as do the other remedies advertised, stating that the product has not been evaluated by the FDA and is not intended to diagnose, mitigate, treat, cure or prevent any disease. Semtical.com does include claims of efficacy, including testimonials, that suggest clinical trials. The page suggests that people should see improvement in symptoms in seven to ten days and indicates a “complete Inclusion Body Myositis cure rate in 90% of subjects”, further stating a response rate of 85% in people with severe cases.

As seen in the under cover purchase video, Preleton .com does not appear to include the disclaimers seen in video of the other purchases. The page states that its formula is “backed by clinical research and trials extending over eight years” and advertises a 92% effect, whatever that means. The "research" page for Preleton.com shows results of two

clinical studies. The first result describes the study as "preliminary" and states "further research should be conducted for confirmation". The next results also states that the study is "preliminary" and concludes that "Based on this data it is believed that if the medication protocol period was longer, the results would have been even better." While there are no obvious disclaimers the language used to describe the clinical studies clearly conveys that the product is not FDA approved.

Each of these drugs was purchased through CCNow, which prominently displayed its own disclaimers which it required purchasers to acknowledge before finalizing their purchase.

On the whole the pages make statements intended to induce consumers to make a purchase – they are *not* made with an intent to defraud. Statements about efficacy cannot be viewed in isolation and must, instead, be viewed in light of the plain language disclaimers that would put any consumer on notice that claims of efficacy should be viewed with skepticism. Nothing on the websites indicated any FDA approval for the drugs but rather clearly and unambiguously alerted potential consumers to the lack of such approval. Buyers were well informed about what they were *not* buying. While the government does not allege false representations of FDA approval as basis of the indictments, the plain statement of non-FDA approval is significant when evaluating fraudulent intent of other statements contained in the pages.

The determination of whether and to what extent advertising is misleading relies on an analysis of language used and a myriad of other considerations, including how consumers actually discount advertising claims based on their own experiences. "The law does not presume that consumers assume that all OTC drug advertising claims are substantiated."

Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc., (902 F.2d 222, 229) (3d Cir. 1990)(*overturned on other grounds)*[3]. While Sandoz was a civil case, the spirit of this dicta states the obvious – consumers of over the counter drugs are wary of advertising claims.

In U.S. v. Vitek (144 F.3d 476)(7th Cir. 1998), the defendant company was charged with smuggling non-FDA approved Drugs into the US for inclusion in "premixes" for veal calves. The drugs were either misrepresented or not included on US Customs documents. Eventually a customer told the US government about the drugs in the premixes. A search warrant was issued and the drugs were uncovered. The defendant was charged with smuggling or receiving smuggled merchandise and distributing adulterated or misbranded animal drugs with intent to defraud. In Vitek, the government conceded that where customers were aware that the product contained unapproved drugs, those customers were in fact, not defrauded. "..[D]irect customers were aware that the premixes contained unapproved drugs. Therefore, as the government concedes, these customers were not defrauded and the defendants cannot be held liable for their losses." Id. at 491.

Similarly, in United States v. Andersen, (45 F3d 217) (7th Cir.) (1995), the Court ordered that there was no quantifiable loss where consumers were very pleased with defendant's product, even though defendant sold said product without FDA approval and made false statements to consumers about the product. United States v Bhutani, (266 F3d 661, 670)(7th Cir.) (2001) mentions the rationale for the Andersen judgment: "However,

[3] The issue presented in Sandoz was what burden of proof the plaintiff bore in a civil action seeking injunction under the Lanham Act. The precise holding is inapt here: "We hold that it is not sufficient for a Lanham Act plaintiff to show only that the defendant's advertising claims of its own drug's effectiveness are inadequately substantiated under FDA guidelines; the plaintiff must also show that the claims are literally false or misleading to the public." 902 F.2d 222, 229 (1990). The case was overruled in 2007 by Pennsylvania Employees Ben. Trust Fund v. Zeneca Inc., (499 F.3d 239)(3rd Cir. 2007).

the defendant points out that in Andersen we held that the defendant's gain was not the appropriate measure of loss when there was "no clear evidence that customers or consumers suffered any loss." Andersen at 221. "We so held, in part, because the drugs in that case were sold in hand-labeled containers and the customers were aware that the drugs were not FDA approved."

For the population of consumers that believes in herbal and homeopathic medicine, the non-FDA approval and statements of efficacy would not influence their purchase – they were not defrauded because they purchased the substance believing it would work and not because it is an FDA approved drug. And for many it did work. Included among the emails and customer service files provided in discovery are comments from customers who found the remedies efficacious and believe they benefited from their purchase.

There were also customers who expressed that they saw no improvement of their symptoms and requested the advertised refund. For those consumers Mr. Arif directed CCNow to issue full refunds, including shipping fees. The remedies were, in fact, guaranteed because a full refund was given to those unsatisfied with their purchase. Bank records provided by the government demonstrate that between 2007 and 2012 MAK issued millions of dollars in refunds.

The government has previously stated that the fraud case is not based on misrepresentation of FDA approval of the drugs but on misrepresentations of the efficacy of the remedies. For the reasons stated, that theory must fail. Knowing and willing buyers of non-FDA approved drugs are not defrauded, even when an unapproved drug fails to meet their expectations in terms of efficacy.

VI. Where drugs belong to bona-fide school of medical practice sincerely believed in by defendant, an intent to defraud does not exist

Regardless of the truthfulness of statements made with the purpose of encouraging consumers, Mr. Arif believed in the efficacy of the products he marketed, the formulation of which is well-established in the herbal and homeopathic schools of medicine. Allegations of fraud are not sustainable as a matter of law when bona fide differences in medical opinion exist. *See* American Sch. of Magnetic Healing v. McAnnulty, 187 U.S. 94 (1902). The products at issue belong to the herbal and homeopathic schools of medical thought. While not as common in the United States as in some other countries and cultures, traditional medicine is well established and widely accepted by vast swaths of the global population as providing treatment and cure for human health ailments, both serious and mild.

Judicial notice may be taken of the example that GMP and ISO certified companies like Qarshi and Hamdard in Pakistan operate on par with modern pharmaceuticals and produce traditional herbal medicine that are utilized in the treatment of human health ailments by countless traditional health practitioners and millions of consumers for all kinds of medical ailments.

The government's case appears to be rooted in the theory that false claims of possession of scientific proof in promotional literature intended to induce the purchase of the drugs are sufficient upon which to find a criminal intent to defraud regardless of one's sincerely held belief in the ability of the product to match customer's expectations. To conclude that false claims of product testing made with the knowledge of their falsity is itself sufficient to conclude an intent to defraud is a fatal failure to distinguish between the knowledge and intent elements of a crime. "[B]ecause there are several areas of criminal

law in which there may be good reason for distinguishing between one's objective and [one's] knowledge, the modern approach is to define separately the mental states of knowledge and intent... This is the approach taken in the Model Penal Code [Sec. 2.02(2)(a) & (b)]." Wayne R/ LaFave & Austin W. Scott, Jr., Criminal Law 218 (2d ed. 1986). *See also* Rutanen v. Baylis (313 F.3d 9, 19)(1st Cir, 2002) "Obtaining money, goods or services by criminal fraud or false pretenses also requires knowledge and more: a specific intent to defraud. E.g., 18 U.S.C. § 1341 (2000) (mail fraud); United States v. Sawyer, 239 F.3d 31, 40 (1st Cir. 2001).

In the present case, Mr. Arif denies an intent to defraud. The government repeatedly claims that in any one given series, the websites were identical, the only difference being the name of the remedy and the disease/condition it was formulated to treat. This creates a false impression that no effort was made to specifically formulate remedies for particular conditions, implying that the same remedy was included on each website in a given series of websites. This is simply not true. A review of the ingredient pages provided in discovery shows that the ingredients and formulation for each remedy is different, despite presence of similar components or combinations of components in more than one product. This goes against the government assertion that each website marketed an identical product.

In the absence of evidence of an intent to defraud consumers, it remains wholly unclear why the government as so vigorously pursued Mr. Arif. The FDA homepage includes a link to "warning letters", which leads to a further link for Drug Marketing and Advertising Warning Letters. A quick review of the letters issued in just the last five years (data and letters are available dating back to 1998) reveal that the FDA issued warning

letters to numerous companies accused of misbranding drugs or making misleading statements in advertising materials about drug efficacy, including companies marketing herbal and homeopathic remedies identical to those at issue here. None of those companies faced criminal charges.

U.S. v. Cole is an example of the lengths the FDA has gone in other instances of far more egregious conduct than that alleged here without pursuing criminal charges. Cole is a civil case in which the FDA sought an injunction against defendant drug company Maxam, which it accused of introducing unapproved, misbranded and adulterated dietary supplements into interstate commerce. The drugs were advertised as treatment of disease such as HIV, Alzheimer's and autism. The FDA took issue with the webpages used to advertise Maxam's products, which included "testimonials" as well as non-testimonial statements indicating efficacy of the drugs. The FDA first sent Maxam a warning letter in 2010. In 2012 the FDA conducted an inspection of the Maxam manufacturing facility in 2012. Following the inspection the FDA advised Maxam of numerous issues at the plant and again warned them about ongoing concerns about disease claims on the websites. Maxam represented that the language had been or would be remedied. Months later the FDA sent yet another letter warning that the proposed response to the manufacturing issues was insufficient and again warning of issues with language on the website. Another facility inspection followed in early 2013 and, again, Maxam was warned about disease claims on the webpages. Again, Maxam represented that all disease claims had been removed from the webpage. More than a year later, after the FDA filed court action, Maxam webpages still contained disease claims.

It took nearly three years before the FDA initiated court involvement and even then, it did not pursue criminal charges. Even after the matter was pending in court Maxam continued to publish statements on their website including a claim that their products could, "eliminate the toxins produced by unhealthy bacteria" and "counteract even overdose of otherwise legal drugs." Cole at 1159. Still, no criminal charges were ever filed.

Here, the government sent no warning letter. They made no attempts to contact Mr. Arif or MAK International and advise them of how to bring the webpages into compliance. The government skipped all administrative measures to attempt to encourage compliance. The government never contacted Mr. Arif about their concerns. The government never gave Mr. Arif or MAK International the opportunity to take corrective action. Instead, federal agents first raised their concerns as they arrested Mr. Arif shortly after he landed in New York for a business trip. He has now been in custody for over 27 months.

This is even more puzzling because the government is now unable to articulate how or why or just when MAK International came to be the subject of FDA investigations. Discovery does not include consumer complaints to the FDA or any other U.S. federal agency. The one actual consumer alleged in this case, the only person in discovery who actually purchased an MAK product, never complained and, indeed, only recounted the sale after being sought out by federal agents.

For all the reasons set forth above, the Court should dismiss the pending indictments. WHEREFORE, it is respectfully requested that the Honorable Court issue an order:

- Dismissing all counts; OR
- Scheduling a hearing. Issuing written findings of fact and rulings of law.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Robin D. Melone, hereby attest that a true copy of the foregoing has been e-filed and copied to AUSA Arnold Huftalen and Attorney Sarah Hawkins on this the 20th day of May, 2016.

/s/Robin D. Melone
Robin D. Melone